

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 1/00, 27/00		A1	(11) International Publication Number: WO 00/21586
			(43) International Publication Date: 20 April 2000 (20.04.00)
(21) International Application Number: PCT/GB99/03392		(81) Designated States: CA, DE, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 13 October 1999 (13.10.99)			
(30) Priority Data: 9822341.5 13 October 1998 (13.10.98) GB		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(71) Applicant (for all designated States except US): KCI MEDICAL LIMITED [GB/GB]; Two Rivers, Station Lane, Witney, Oxfordshire OX8 6BH (GB).			
(72) Inventors; and			
(75) Inventors/Applicants (for US only): HUNT, Kenneth, William [GB/GB]; 18 Egdon Drive, Merley, Wimborne, Dorset BH21 1TY (GB). HEATON, Keith, Patrick [GB/GB]; 33 Hermitage Road, Poole, Dorset BH14 0QG (GB).			
(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).			
(54) Title: NEGATIVE PRESSURE THERAPY USING WALL SUCTION			
(57) Abstract			
<p>Apparatus is disclosed for applying negative pressure therapy to a wound site, which comprises an open celled foam pad (1) for application to the wound, a suction tube (2) connecting the foam pad to a collection canister (3), said canister having a shut-off valve (140) which closes the outlet from the canister when it is full, a tube (4) for connecting the canister to a wall suction point (7) and a pressure detecting means (10) connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

NEGATIVE PRESSURE THERAPY USING WALL SUCTION

This invention relates to negative pressure therapy and provides a device which can be used to provide such therapy on connection to an existing source of suction, such as a vacuum line.

Our prior patent application WO 97/18007 describes portable wound treatment apparatus for stimulating the healing of wounds. The apparatus described in our above application comprises a porous pad, which is permeable to fluids, for packing into or over the wound, dressings for covering and for providing an air-tight seal around the wound, and a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, a canister being provided for collecting fluids which are sucked from the wound.

The apparatus described in our above application can be worn by the patient on a harness or sling so that he is not confined to one particular place while the therapy is in progress. There is, however, a demand for a more basic piece of equipment which, although not as sophisticated as the equipment described in our above application, does provide some of the benefits of negative pressure therapy.

Most hospitals have a suction line which is fed to all the wards and is available to nursing staff for a variety of purposes, such as powering drainage tubes and suctioning body fluids generally. For such uses, a pressure regulator may be connected to the source of suction and this regulator may include a pressure gauge indicating the pressure at the regulator valve. It is, however, dangerous to connect such a suction source directly with a patient, without providing continuous supervision. In many hospitals, shortage of staff makes it difficult or impossible to

provide adequate close supervision, and if attempts are made to use such a source for negative pressure therapy, there is a very real danger of injuring the patient.

In some hospitals, vacuum bottles may be employed to assist drainage from wounds, e.g. after operations. Such bottles are containers which are available in various capacities and which are evacuated to low pressure. Vacuum bottles can be used in accordance with the invention as an alternative to a wall suction point. They have the advantage of providing a greater degree of portability to the negative pressure therapy apparatus, but the disadvantage that the bottle needs to be replaced with a fresh bottle once the pressure in the bottle has increased to the vicinity of ambient pressure.

An object of the present invention is to provide equipment which can be used with an existing wall suction source to safely provide negative therapy to patients.

According to one aspect of the present invention there is provided apparatus for applying negative pressure therapy to a wound site, said apparatus comprising an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full, a tube for connecting the canister to a wall suction point or a vacuum bottle and a pressure detecting means connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level. The pressure detecting means may be a transducer which is connected by a branch tube to the suction tube leading from the foam pad to the canister. The transducer may be set to generate a visible and/or audible warning when the pressure in the suction tube falls below a pre-set level. A

sudden pressure drop in the suction line would indicate that the canister is full and, consequently, there is no longer any effective therapy being applied to the therapy.

The canister full situation would normally be indicated by substantially zero pressure in the suction line. The transducer may also be set to activate a warning in the event that the pressure in the suction line does not reach a minimum pre-set pressure, or the pressure rises towards atmospheric after suction has initially been established, thereby indicating a gross leak in the system.

Preferably, the apparatus also includes a flow limiter in the line connecting the canister to the wall suction source so as to prevent the flow in the suction tube exceeding a pre-set level.

The apparatus may include a display panel which indicate the pressure existing at any one moment in the suction line. The transducer may also be adjustable so that indication or warning is given at different pre-set pressures.

The apparatus as described above may be adapted to give intermittent pressure therapy by providing a relief valve in a tube leading from the suction line. This relief valve may be programmable by a processor so that it is openable and closeable according to a pre-set programme thereby providing intermittent negative pressure therapy to the wound site.

Further features described below may also be introduced into the apparatus as described to give further desirable features.

Several embodiments in accordance with the invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic representation of one embodiment in accordance with the invention;

Figure 2 is a diagrammatic representation of a second embodiment; and Figures 3A & 3B are diagrammatic representations of a collection canister for monitoring rates of flow of fluids sucked from the wound.

Referring to Figure 1 of the drawings, the apparatus for applying negative therapy comprises a foam pad (1) which is applied over or packed into a wound to be treated and is connected by a suction tube (2) to a canister (3). The canister (3) may be of conventional design having a shut-off valve (shown diagrammatically at (140), which automatically closes once the canister is full. The foam pad may comprise any suitable interconnected cellular foam. Foams which have been found to be especially suitable are polyurethane and polyvinyl alcohol foams or combinations thereof, having interconnected cells.

As shown in Figures 1 and 2, the foam pad is packed into the open wound and connected to the negative pressure source by a connector device (100) comprising a flexible backing plate (110) and an integral connector tube (120). The connector tube (120) is dimensioned internally to receive the suction tube or tubes (2) as a substantially air-tight fit. The foam pad and connector combination is secured to the wound to be treated by a surgical drape (130), which may be formed with an aperture to permit the tubular part (120) of the connector to pass through the drape.

A connector of this kind is described in UK Patent Application No. 9819678.5, WO 99/ 13793 and the corresponding US Patent Application filed on 9

July 1999 (attorney ref: 1009.1094) entitled "Surgical drape and suction head for wound treatment", the disclosure of which is specifically incorporated herein.

A suitable canister of this kind is described in WO 97/18007, European Patent Application No. 0358302 or in US Patent Application No. 09/078223, the disclosure of which is specifically incorporated herein.. The canister is also connected via a further tube (4) to a pressure regulator (5). The pressure regulator carries a gauge (6) and is connected to an existing vacuum line such as a standard hospital wall suction source (7). In many hospital installations a regulator valve (5), together with a pressure gauge (6) already exist, attached to an existing suction source or can be fitted to an existing outlet in the suction source supply. The apparatus may also include an optional flow limiter (8), which may be adjusted to provide different desired levels of flow in the system.

Pressure in the suction tube (2) is measured by a branch tube (9) which is connected to the suction tube and to a transducer (10). The transducer (10) is mounted on a process control board (12) and this may be connected to a visual display (13). An optional relief valve (11) may also be connected into the tube (9) and provide a means for controlling the level of negative pressure at the wound site. The relief valve (11) may be manually settable so that the pressure at the wound site does not exceed a predetermined figure. In a more esoteric version, the relief valve may be electronically controlled from the PCB to relieve pressure at the wound site at pre-settable maximum pressures. Many hospitals, in addition to having a suction source and a pressure regulator such as regulator (5), also have body fluid collection canisters (3) supplied for other purposes. It may, therefore, be possible to supply to the

hospital apparatus included in the dotted line shown in Figure 1, together with foams and connecting tubes so that they can connect the existing apparatus to a canister and a regulator (5) available in the hospital.

A more elaborate system is shown in Figure 2, which is similar to the arrangement shown in Figure 1 except for the following features described below. The same reference numerals indicate features common to both embodiments. First, the pressure regulator 15 connecting the apparatus to the wall suction source 17 is electronically controlled by the process control board (12). Secondly, the pressure at the wound site is monitored by a transducer (20), while the pressure in the tube connecting the canister to the regulator is measured by a transducer (21). The transducer (20) is connected to the wound side by a tube (23). Instead of providing separate tubes (2) and (23), a single bi- or multi-lumen tube may be used as described in our co-pending application WO97/18007. A relief valve (24) communicates with the tube (23) and enables the apparatus to operate intermittently in a controllable manner by intermittently reducing flow through the regulator (8) and venting pressure through the valve (11). The canister full situation is detected by noting a pressure differential between transducer (20) and transducer (21), or by means of a separate fluid level sensor. Pressure detection at the wound site via the transducer (20) also indicates whether there is a pressure leak or no therapy. A custom-made canister (32) may include means for sensing electronically when the canister is full and must be replaced, e.g. by capacitance measuring means (34). Preferably, the canister is designed to fit into a recess in a custom made housing (30), indicated by dotted lines.

The housing may be directly connected at one end to the wall suction point (7), and at the other to a tube or tubes leading to the foam pad (1) at the wound site.

In the embodiment of Figure 2, the transducers (20 & 21), the relief valve (11) and pressure regulator (8) are preferably all electronically controlled by connections to the PCB. For example, the canister full situation is detected by comparison of the pressure difference between transducers (20 & 21) and this can be signalled on the display (13) and, optionally, also by an audible warning signal.

It may be desirable to measure the rate at which fluids are sucked from the wound site. This is conveniently achieved by measuring the rate at which the canister is filled with wound exudate. A suitable device is shown diagrammatically in Figure 3. In one configuration shown in Figure 3A, a sleeve (33) is held in intimate contact with the outer surface of the canister. This sleeve carries a single sensing element (35), e.g. capacitive sensor that can provide a means of sensing the presence of liquid at different levels in the canister by simply moving the sleeve up and down the canister. The sensing element detects the presence of liquid by projecting an electrical field into the canister and detecting any change in that field, e.g. by a change in capacitance. The rate of change of capacity over the portion of the canister surveyed by the detector gives an indication of rate of flow of fluid sucked from the wound site.

In another configuration shown in Figure 3B, a series of sensing elements (36) are evenly spaced on a sleeve (33) that is in contact with the outer surface of the canister. As the fluid level rises within the canister, the sensing elements are triggered. This information can then be used by the control system at the PCB to deduce flow rate.

CLAIMS:-

1. Apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full, a tube for connecting the canister to a wall suction point or to a vacuum bottle, and a pressure detecting means connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level.
2. Apparatus as claimed in claim 1 which includes a flow limiting valve disposed between the canister and the suction source.
3. Apparatus as claimed in claim 1 or 2 which includes a pressure relief valve which is connected to the suction tube between the foam pad and the canister.
4. A modification of the apparatus as claimed in any one of the preceding claims which includes a first transducer for measuring pressure in a tube linking the canister to the wall suction point or to a vacuum bottle, and a second transducer for measuring pressure at the wound site.
5. Apparatus as claimed in any one of the preceding claims which includes flow rate measuring means for measuring the rate at which fluid is sucked from the wound site.
6. Apparatus as claimed in claim 6 in which the flow rate measuring means comprises a device for measuring the rate at which the canister is filled.
7. Apparatus as claimed in claim 6 in which the flow rate measuring means is an electrical capacitance measuring device.

8. Apparatus for applying negative pressure therapy to a wound site, which comprises an open-celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, a tube for connecting the canister to a wall suction point or a vacuum bottle and means for sensing when the canister is full.

9. Apparatus according to claim 8 which includes means for giving a warning that the canister is full and/or shutting off the connection between the canister and the wall suction point.

10. Apparatus according to claim 8 or 9 which further includes means for monitoring pressure at the wound site.

11. Apparatus according to any one of claims 8 to 10 which further includes means for regulating pressure between the canister and the suction source.

1/3

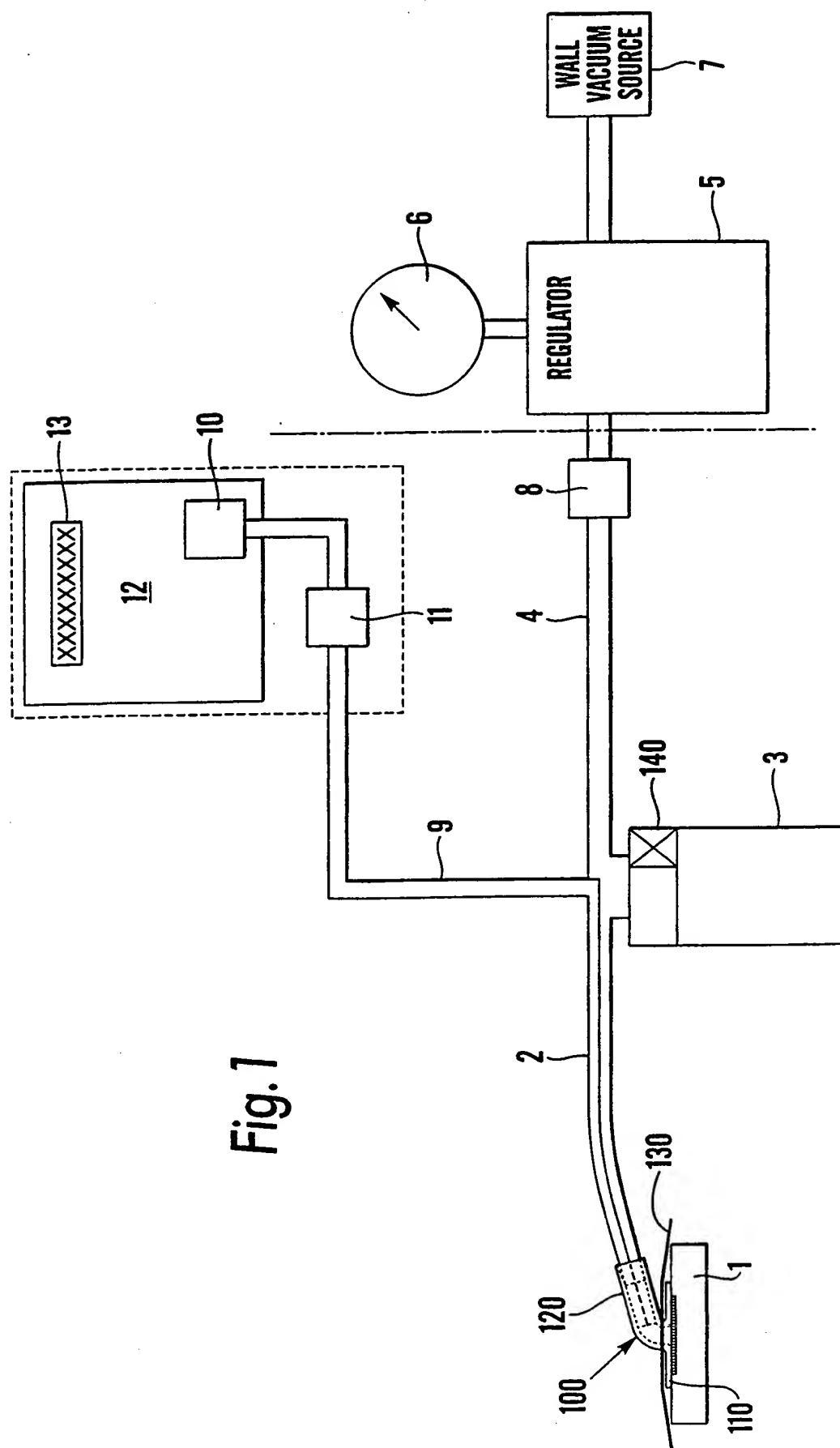


Fig. 1

2/3

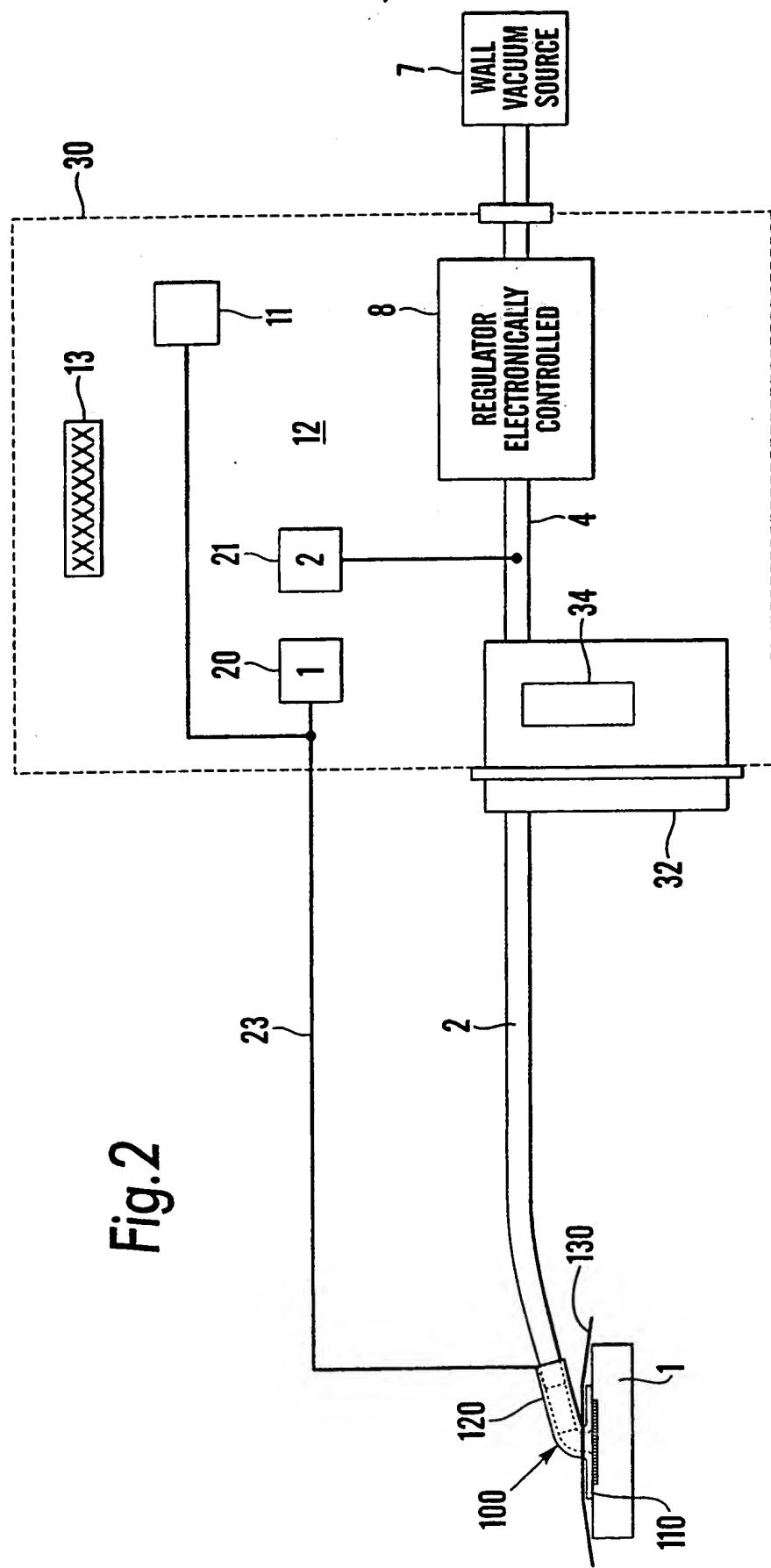


Fig. 2

3/3

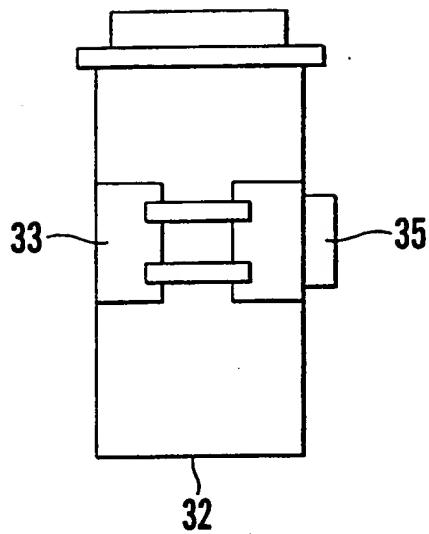


Fig.3A

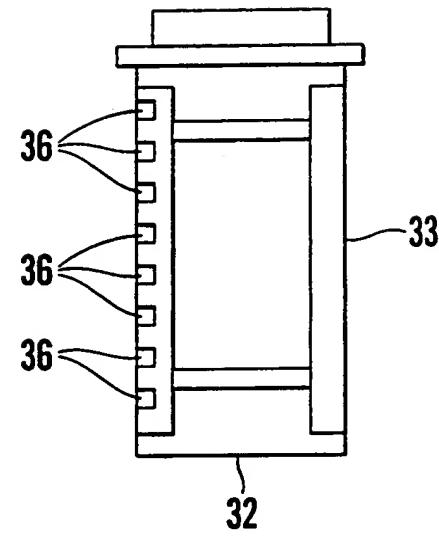


Fig.3B

INTERNATIONAL SEARCH REPORT

National Application No

PCT/GB 99/03392

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61M1/00 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search, (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 05873 A (MEDISCUS PROD LTD ;HEATON KEITH PATRICK (GB); LINA CESAR Z (US); K) 29 February 1996 (1996-02-29) page 7, paragraph 4 page 11, paragraph 4 -page 12, paragraph 1 page 16, paragraph 4 -page 17, paragraph 2 page 18, paragraph 4 -page 19, paragraph 1 figures 5,6,9	8-11
A	---	1,2,4-7
X	WO 97 18007 A (KCI MEDICAL LTD ;HEATON KEITH PATRICK (GB); HUNT KENNETH WILLIAM (GB) 22 May 1997 (1997-05-22) cited in the application page 5, paragraph 4 -page 6, paragraph 3 figure 1	8-11
A	---	1,3,4
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

2 February 2000

Date of mailing of the international search report

09/02/2000

Name and mailing address of the ISA
 European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Lakkis, A

INTERNATIONAL SEARCH REPORT

atational Application No

PCT/GB 99/03392

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 636 643 A (ARGENTA LOUIS C ET AL) 10 June 1997 (1997-06-10) column 5, line 43 - line 44 column 8, line 20 -column 9, line 52 figures 1,7-9 -----	8,9,11
A	-----	1,2
A	GB 2 235 877 A (TALLURI ANTONIO) 20 March 1991 (1991-03-20) page 4, line 21 -page 6, line 23 -----	1,2,5,6, 8,9,11
A	DE 197 22 075 C (FLEISCHMANN WILHELM DR MED) 1 October 1998 (1998-10-01) column 4, line 15 - line 29 figure 1 -----	1,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No

PCT/GB 99/03392

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9605873	A 29-02-1996	AT 172377 T AU 698477 B AU 3349995 A CA 2198243 A DE 69505545 D DE 69505545 T EP 0777504 A EP 0853950 A JP 10504484 T ZA 9506968 A		15-11-1998 29-10-1998 14-03-1996 29-02-1996 26-11-1998 11-03-1999 11-06-1997 22-07-1998 06-05-1998 29-03-1996
WO 9718007	A 22-05-1997	CA 2237606 A DE 19681649 T DE 29623482 U EP 0865304 A GB 2307180 A GB 2336546 A		22-05-1997 03-12-1998 23-07-1998 23-09-1998 21-05-1997 27-10-1999
US 5636643	A 10-06-1997	US 5645081 A AU 696031 B AU 6360894 A CA 2157772 A EP 0688189 A JP 9503923 T WO 9420041 A AT 164055 T AU 674837 B AU 3130393 A CA 2121688 A DE 9219136 U DE 69224847 D DE 69224847 T EP 0620720 A ES 2114956 T JP 7501958 T WO 9309727 A		08-07-1997 27-08-1998 26-09-1994 15-09-1994 27-12-1995 22-04-1997 15-09-1994 15-04-1998 16-01-1997 15-06-1993 27-05-1993 18-06-1998 23-04-1998 20-08-1998 26-10-1994 16-06-1998 02-03-1995 27-05-1993
GB 2235877	A 20-03-1991	NONE		
DE 19722075	C 01-10-1998	EP	0880953 A	02-12-1998